REMARKS

Claims 1 and 8 are amended herein. Support for the amendment is found, for example, on page 5, lines 7-11, page 6, lines 16-20. No new matter is added. Accordingly, upon entry of the Amendment, claims 1, 4-8, 11 and 12 will be all of the claims pending in the application.

I. Response to Claim Rejection under 35 U.S.C. § 103

Claims 1, 4-8, 11 and 12 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ueda et al (U.S. Patent No. 5,045,553) in view of Woo et al (U.S. Patent No. 6,455,067 B1).

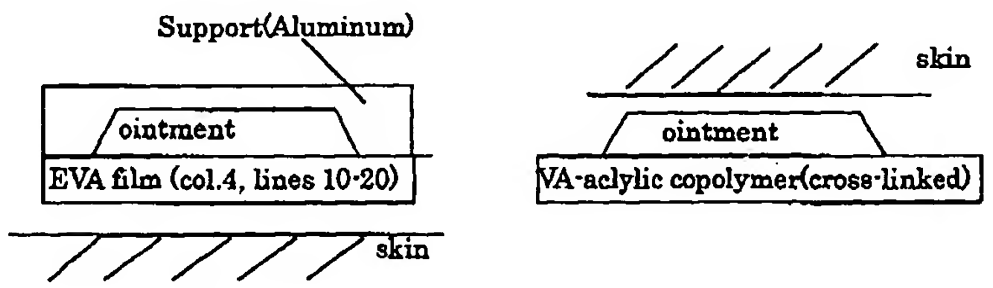
Applicants respectfully traverse the rejection and submit that the cited references do not teach or suggest the presently claimed invention.

In the response filed November 23, 2004, Applicants pointed out that one of ordinary skill in the art would not have been motivated to combine the references because Woo discloses an external patch specifically for a nonsteroidal anti-inflammatory drug (NSAID), whereas Ueda et al discloses a patch preparation for a dihydropyridine compound, which is not an NSAID. The Examiner asserts that this argument is unconvincing, because the present claims do not recite a drug. However, the argument was made to traverse the alleged combination of the cited references, and not to distinguish the present invention from the cited references. There is no requirement that lack of motivation to combine be based upon claimed features and therefore Applicants can rely on unclaimed features to show that there is no motivation to combine references.

In view of the above, Applicants submit that the Examiner has not made a *prima facie* showing of obviousness. To establish a *prima facie* case of obviousness, there must be suggestion or motivation to make the combination in the prior art. See MPEP 2142. In the present case, since one of ordinary skill in the art would not have been motivated to utilize the Woo patch for a non-nonsteroidal anti-inflammatory drug such as a dihydropyridine compound disclosed in Ueda et al, there is no motivation to combine Woo et al and Ueda et al. Therefore, the Examiner has not met her burden to provide any suggestion or motivation for a *prima facie* case of obviousness.

Even if the references were combined the presently claimed invention would not have been achieved. As previously pointed out, the EVA film of Ueda does not correspond to the support of the present invention. The Examiner asserts that Ueda teaches an EVA film layer on an aluminum support at column 4; however, it is clear from the description at column 4, lines 15-32, that the EVA film layer is used for sealing the pharmaceutical composition and controlling the rate of drug absorption from the pharmaceutical composition, e.g., the solution gel of Ex. 12. Rather, Ueda has distinguished the aluminum support from the absorption promoter layer as in the Figures, description (col. 2, line 36, col. 3, line 34, col. 4, lines 6, 13 and 39) and Examples. Furthermore, it is clear that the aluminum support of Ueda does not have the properties of the support of the present invention as recited in independent claims 1 and 8. Particularly, the support of Ueda does not have the water vapor permeability property of the claimed invention and since the support of Ueda is metallic, it does not have the properties of permeability to air, modulus and stretching of 50% or more as in the present invention.

In addition claims 1 and 8 are amended herein to recite that the support is impermeable to the ointment. In contrast, Ueda teaches an aluminum support coated with an ointment and the ointment is covered with EVA film, wherein the EVA film is between the ointment and the skin. Therefore, the EVA film of Ueda corresponds to an intermediate layer between an ointment coated surface of the support and the skin, which is avoided in the present invention as described in the specification on page 5, lines 7-20. In the present specification, it is disclosed that the ointment patch of the present invention, which does not include any layer structure between the ointment coated surface of the support and the skin, is capable of applying ointment directly to the skin and thereby prevents reduction in its drug releasability. Page 5, lines 7-13. It is further disclosed that without the intermediate layer, the ointment patch of the present invention further achieves improved adhesion to the skin. Page 5, lines 18-20. The following illustration is provided to show the structural differences between Ueda and the claimed invention.



Ueda Ex. 12 Present invention

In view of the above, one of ordinary skill in the art would not have expected to achieve, nor would the presently claimed invention have been achieved based on the disclosure of Ueda. Further, as discussed above, there is no motivation for one of ordinary skill in the art

to combine Ueda and Woo, and even if the references were combined, the present invention would not be achieved because Woo does not cure the deficiencies of Ueda.

Woo discloses a patch comprising a support and a solid including a non-steroidal anti-inflammatory drug (col. 6, lines 25-37), wherein the solid is prepared by stably diffusing the non-steroidal anti-inflammatory drug in a water containing base (col. 3, lines 7 -19). The Examiner asserts that the synthetic polymer comprising a polyvinyl acetate-acrylic acid copolymer is used to strengthen water retention and so on. However, the copolymer of Woo is merely used as one of the additives incorporated into the solid. It is not used in a film nor used as the support. Further, Woo is completely silent about the water vapor permeability regarding the additives disclosed at column 6, lines 5-19, and does not disclose the water vapor permeability of the copolymer itself. Therefore, there is no motivation for one of ordinary skill in the art to combine the references with a reasonable expectation of success in achieving the claimed invention.

In addition, both the EVA film of Ueda and polyvinyl acetate-acrylic acid component of the Woo are permeable to the ointment, whereas the support film of the present invention is impermeable to the ointment. One of ordinary skill in the art would not have been motivated to modify or combine the references in this regard because such modification would render the patches of Ueda and Woo unsuitable for the intended purpose, because the ointment would not be able to reach the skin as intended if the EVA film of Ueda and/or the acetate-acrylic acid component of Woo were modified to be impermeable to the ointment.

Finally, Applicants have already pointed out that the polyvinyl acetate-acrylic acid copolymer of Woo is not cross-linked as in the present invention and therefore, even if the

references were combined the claimed invention would not be achieved. In this regard the Examiner asserts that the claims do not require cross-linking of the vinyl acetate-acrylic acid copolymer since the claims allow for there to be no vinyl acetate and no (meth)acrylic acid in the copolymer; thus no cross-linked copolymer would result. However, Applicants submit that the Examiner misunderstands the cross-linking of the polymer. It is clearly disclosed in the present specification that the process of forming cross-linkages in the copolymer of the present invention involves applying UV or gamma rays or by adding a cross-linking agent. See page 8, lines 15-21. This means that a cross-linking agent is not always required to provide a cross-linked polymer within the scope of the present claims. Particularly, in the case of cross-linking by UV or gamma rays, the copolymer is cross-linked with 0% (meth)acrylic acid. Vinyl acetate is not an essential component for cross-linking and therefore there is no problem to form a cross-linked polymer using a very low content of vinyl acetate in the copolymer.

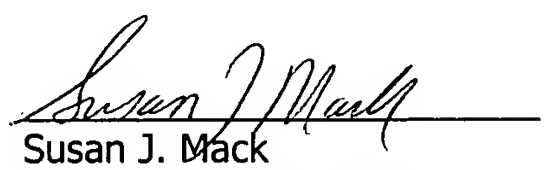
In view of the above, the presently claimed invention is not rendered obvious by Ueda and Woo, taken alone or in combination. Accordingly, Applicants respectfully request withdrawal of the rejection.

II. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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